M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: February 8, 2000

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: Filing Review and Legal Issues for Abbreviated New Drug Applications (ANDAs)

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation:	Filing Review and Legal Issues for Abbreviated New Drug Applications (ANDAs)
Presented for:	1999 Fall Technical Workshop
Date Presented:	10/18/99
Presented by:	Peter Rickman
Number of Pages:	21

M. Lamb

Attachment

90S-0308

M655

Filing Review and Legal Issues for Abbreviated New Drug Applications (ANDAs)

October 18, 1999
1999 Fall Technical Workshop

Peter Rickman

Deputy Director

Division of Labeling and Program Support

Office of Generic Drugs

Outline

- Guidances
- RTF Issues
- Paragraph IV Patent Certifications

GUIDANCE FOR INDUSTRY ORGANIZATION OF AN ANDA

- Revises the guidance for industry on this topic issued in April 1997, which replaced the OGD PPG #30-91
- Recommended organization of ANDAs and related submissions
- Proper format enables the reviewer to review the submission more efficiently

REVISIONS

- Remove reference to AADAs consistent with FDAMA 1997
- Specific information on the submission of sterility assurance data
- Financial certification/disclosure statement – form 3454 or 3455
- Packaging and labeling procedures and container sections consolidated into a single section – packaging materials controls

GUIDANCE FOR INDUSTRY VARIATIONS IN DRUG PRODUCTS THAT MAY BE INCLUDED IN A SINGLE ANDA

BACKGROUND:

- Prior to OCT. 1990 applicants were to submit separate ANDAs for each strength and variation (e.g., shape or color)
- Historically, applications were separated for ease of review and post approval tracking

VARIATIONS IN DRUG PRODUCTS THAT MAY BE INCLUDED IN A SINGLE ANDA

- New Guidance revises OGD PPG #20-90. PPG #20-90 permitted certain variations of solid oral dosage forms and injectables to be submitted in a single ANDA

- Guidance has been expanded to include ALL dosage forms

DETERMINING WHETHER A SINGLE OR MULTIPLE ANDAs SHOULD BE SUBMITTED

- Reference listed drugs (RLDs)
  Separate NDA'S as RLDs – Generally separate ANDAs

- Multiple bioequivalence studies
  Formulation differences – BE waiver not granted

DETERMINING (Continued)

- Pharmacy bulk packages should always be submitted as separate ANDAs

- Special Packaging
  Novel or new container closure systems should always be submitted as separate

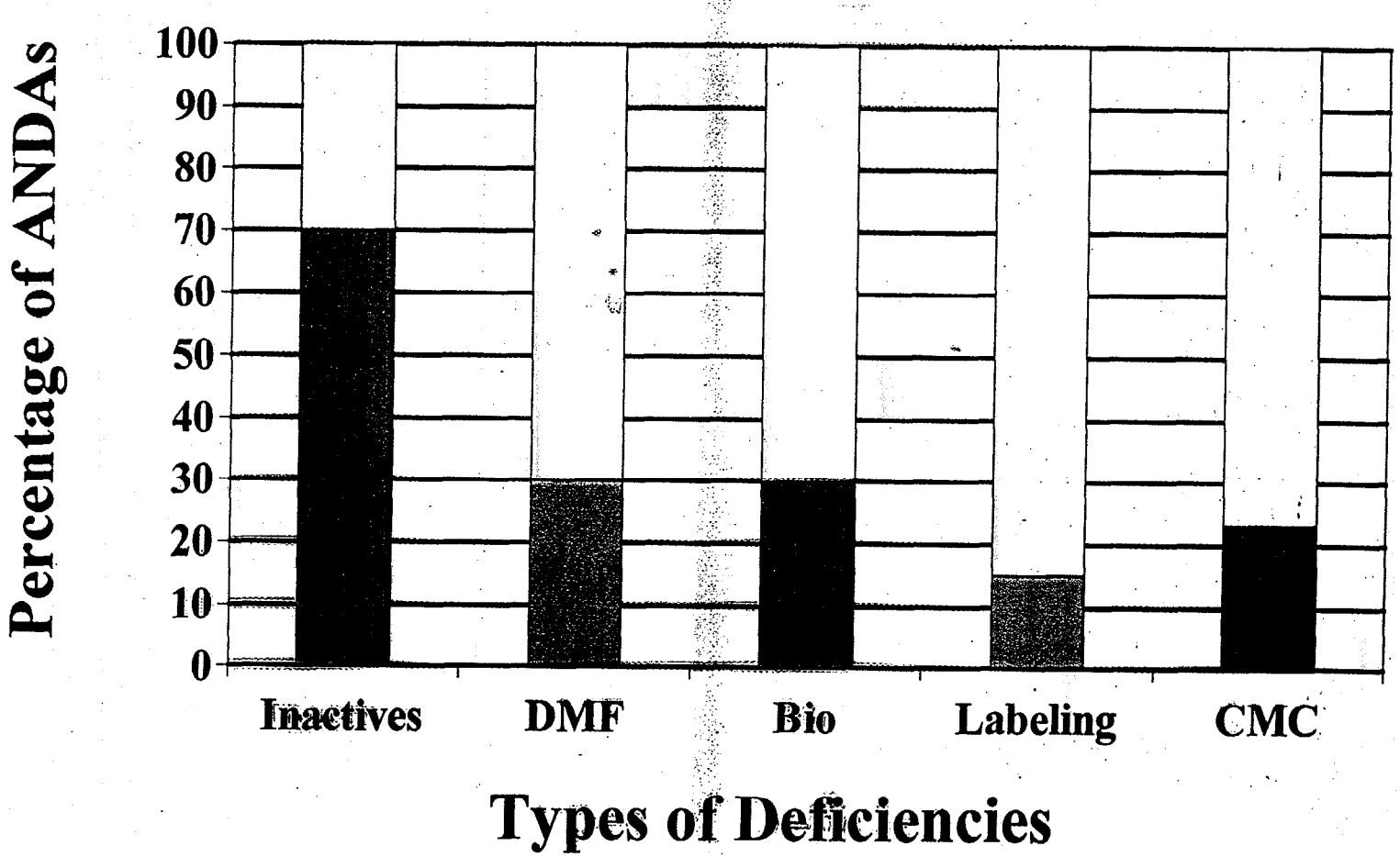
- Transdermal Products

Active ingredient contained in patch adhesive vs. reservoir – separate ANDAs

These Guidances are available on the Internet:

fda.gov/cder/guidance/index.htm

53 RTF letters issued by OGD since January, 1999



INACTIVE INGREDIENTS

THINGS TO AVOID:

- Use of an inactive ingredient that has ***not*** been previously approved
- Use of an inactive ingredient that ***exceeds*** the maximum concentration previously approved
- Use of an inactive ingredient not approved for use in the same ***route of administration***
- Changes in inactive ingredients ***not permitted*** under 21 CFR 314.94 (a) (9)

CMC RTF ISSUES

- Incomplete packaging of the exhibit batch
- Incomplete or missing stability data
- Certificate of analysis (COA) not provided
- No drug master file (DMF) authorization
- Inconsistent lot numbers
- No batch reconciliation

BIO RTF ISSUES

- Incomplete or no BIO data
- No financial disclosure certification/statement
- Incomplete or no dissolution data

LABELING RTF ISSUES

- No container labels for reference listed drug (RLD)

- Did not provide adequate number of copies of proposed labeling

- No side by side comparison

PARAGRAPH IV DISCLOSURE

Potential applicants who wish to inquire whether an ANDA for a specific drug has been received can contact the regulatory support branch at

(301) 827-5862

Be aware that there is a ***30-60 DAY*** lag time for up to date status on receipt of P IV

PARAGRAPH IV DISCLOSURE

WILL disclose whether an ANDA has been received for a particular drug product

WILL NOT disclose when the ANDA had been received

WILL NOT disclose the applicants identity